



October 25, 2007

Dr. Gary J. Buehler
Director, Office of Generic Drugs
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Re: Docket No. 2007N-0389, 180-day Generic Drug Exclusivity for Granisetron Hydrochloride Injection

Dear Dr. Buehler:

Baxter Healthcare Corporation appreciates FDA's invitation to comment on the matter identified above. Baxter fully supports the comments of Teva Parenteral Medicines in its letter of September 28, 2007. In particular, Baxter agrees with Teva that, under the plain language of 21 USC § 355(j)(5)(D)(i)(I), the forfeiture provisions of that statute have not divested Teva of its right to 180-day exclusivity for its 1-mg/mL vials of granisetron hydrochloride, and that the continued potential for a subsequent event under § 355(j)(5)(D)(i)(I)(bb)¹ entitles Teva to retain such exclusivity even though more than thirty months have elapsed since its ANDA was filed. This is true even though any such "subsequent event" could not actually trigger forfeiture if Teva launched before (or within 75 days after) any such event occurred. As long as the possibility exists that a subparagraph (bb) event might someday occur, Teva remains entitled to its 180-day exclusivity because the statute does not trigger a forfeiture of such exclusivity until "the later of" the first event under subparagraph (aa) or any subparagraph (bb) event.

Baxter shares Teva's interest in this matter because, as the first filer of a substantially complete ANDA for the 1 mg/mL, 4 mL multidose vial presentation of granisetron hydrochloride injection, Baxter holds 180-day exclusivity for that presentation subject to the identical risk of a forfeiture event under subparagraph (bb) as described in Teva's letter. Like Teva, Baxter filed its ANDA with a paragraph IV certification as to U.S. Patent No. 6,294,548 ("the '548 patent"); a paragraph III certification as to U.S. Patent No. 4,886,808 ("the '808 patent"); and a certification under § 355(j)(2)(A)(viii) as to U.S. Patent No. 5,952,340. Like Teva, Baxter was not sued by Roche, the reference listed drug's NDA holder, on the '548 patent within the 45-day period provided by § 355(j)(5)(B)(iii) but must still await the expiration of the '808 patent on December 29, 2007 before final approval of its ANDA becomes effective. On that date, Baxter will still be entitled to 180-day marketing exclusivity for the 1 mg/mL, 4 mL vial presentation, even though

¹ In this case, relevant events under subparagraph (bb) could include a non-appealable final judgment, settlement order or consent decree holding the '548 patent invalid or not infringed; or de-listing of the '548 patent from the Orange Book. Such events could result from an infringement action brought by Roche against any ANDA or NDA applicant having tentative approval, even if Roche elected not to file suit within 45 days after receiving the paragraph IV notice, or from a declaratory judgment action brought by the applicant following Roche's failure to file suit.

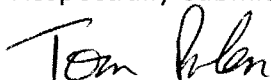
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more than thirty months will have elapsed since Baxter filed its ANDA in June 2004, because none of the still-possible forfeiture events in § 355(j)(5)(D)(i)(I)(bb) will have occurred. Since forfeiture under § 355(j)(5)(D)(i)(I) occurs only upon a first-filer's failure to market by **the later of** a subparagraph (aa) event or a subparagraph (bb) event, Baxter retains its 180-day exclusivity as long as no subparagraph (bb) event occurs before Baxter launches—even if no such event ever actually occurs—because the possibility that such an event may occur in the future operates to keep the pre-forfeiture window open. As Teva correctly notes, any other interpretation of the statute renders subparagraph (bb) a nullity.

Even if FDA chose to interpret § 355(j)(5)(D)(i)(I) as triggering a forfeiture for failure to market within thirty months if no subparagraph (bb) event occurs, Baxter respectfully submits that its failure to market by the thirty-month date provided in § 355(j)(5)(D)(i)(I)(aa)(BB) (i.e., January 19, 2007) should be excused because the '808 patent remains in effect until December 29, 2007, precluding Baxter from launching its granisetron hydrochloride injection product before that date. Inasmuch as the 180-day exclusivity is Baxter's statutory reward for being the first to file an ANDA challenging the scope of the '548 patent, it would be contrary to the intent of the statute for Baxter to forfeit this exclusivity merely because it cannot market its generic granisetron hydrochloride product while a second patent on the reference listed drug remains valid.

For the foregoing reasons, Baxter supports Teva's interpretation of § 355(j)(5)(D)(i)(I), i.e., that the first ANDA filer does not forfeit its 180-day exclusivity by failing to launch within thirty months if there remains any possibility of a subsequent forfeiture event under subparagraph (bb) or if other patents not challenged by the applicant preclude an earlier launch. For that reason, Baxter further respectfully submits that it remains entitled to 180-day marketing exclusivity for the 1 mg/mL, 4 mL multidose vial presentation of granisetron hydrochloride injection. In view of the impending expiration of the '808 patent on December 29, 2007, Baxter joins Teva in requesting that FDA issue its final decision on this matter by December 1.

Respectfully submitted,



Baxter Healthcare Corporation
Tom Polen
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